

REMARKS

Applicant respectfully requests reconsideration and allowance of claims 1 and 4-21 that are pending in the above-identified patent application. By the foregoing amendment, Applicant has amended claims 1, 15, 16, and 17. Applicant cancelled claims 2 and 3 and added new claim 21. No new matter is added by the amendment. In view of the following discussion, Applicant submits that all pending claims are in condition for allowance.

Claim Objections:

At page 2 of the Office Action, the Examiner objected to claim 1 due to several informalities. Specifically, the Examiner alleged that the recitation of “capsule comprising” is not a proper method step to limit capsule structure. Applicant amended claim 1 to recite “providing a capsule containing the composition and comprising a longitudinal axis...” as suggested by the Examiner. As such, Applicant submits that claim 1 properly recites method steps and respectfully requests that the Examiner’s claim objection be withdrawn.

Claim Rejections under 35 U.S.C. §112, second paragraph:

At page 2 of the Office Action, the Examiner rejected claims 1-20 for being indefinite. Specifically, the Examiner rejected claim 1 for failing to provide antecedent basis for several limitations. Applicant has amended claim 1 to provide antecedent basis as suggested by the Examiner. However, Applicant submits that the recitations of “fine structures of any seams” and “angles of taper up to 5°” degrees have sufficient antecedent basis. Further, Applicant amended claim 1 to recite only one “and/or” for grammatical correctness.

Applicant submits that the meaning of the words and/or phrases “fine structures...”, “elements...”, and “angles...” are clear because the “fine structures...”, “elements...”, and “angles...” are features that *form the outer contour of the capsule*. Amended independent claim 1 recites “the following features forming the outer contour of the capsule being excluded from conditions of symmetry...” (Emphasis added.) Indeed, the limitations excluded from conditions of symmetry apply to the features forming the outer contour of the capsule. As such, Applicant submits that the location of the structures is, therefore, clear and that the features being excluded from the conditions of symmetry are part of the capsule being used in the method of amended independent claim 1.

The Examiner further alleges that Applicant claims “[a] method for administering a composition” however, does not lay out proper method steps for administering said composition in the body of the claim. As aforementioned, Applicant amended claim 1 to recite “providing a capsule containing the composition and comprising a longitudinal axis...” As such, Applicant submits that claim 1 properly recites method steps, and that amended independent claim 1 is definite.

At page 3 of the Office Action, the Examiner rejected claims 2-15 for not reciting method steps. Applicant respectfully traverses this rejection. As aforementioned, amended independent claim 1 now properly recites method steps, and claims 2-3 have been cancelled. As claims 4-15 further recite method steps and/or structural details of the capsule or inhaler recited in independent claim 1, they are likewise definite.

Pertaining to claim 5, the Examiner alleged that “the capsule has no elevations” is indefinite because the location of the elevations is not clear. Applicant respectfully disagrees with the Examiner. Applicant submits that the location of the elevations is clear in that there are no elevations on the capsule, i.e., there are no elevations located anywhere on the capsule. As such, Applicant submits that claim 5 is definite.

The Examiner rejected claim 16 for failing to provide antecedent basis for several limitations. The Examiner also alleged that “[a]n inhaler for administering a composition” in line 1 and “produced by the sealing of the seams” in line 8 are confusing as claiming the method of making a capsule structure in an apparatus claim. Applicant has amended independent claim 16 to provide antecedent basis as suggested by the Examiner. However, Applicant submits that the recitation of “angles of taper up to 5” degrees has sufficient antecedent basis. Applicant amended claim 16 to recite “any seams comprising sealed seams...” Applicant submits that “[a]n inhaler for administering a composition” is clear and submits that amended claim 16 does not claim the method of making a capsule structure. Further, Applicant amended claim 16 to recite only one “and/or” for grammatical correctness.

Further pertaining to independent claim 16, Applicant submits that the meaning of the words and/or phrases “fine structures...”, “elements...”, and “angles...” are clear because the “fine structures...”, “elements...”, and “angles...” are features that *form the outer contour of the capsule*. Amended independent claim 16 recites “the following features forming the outer contour of the capsule being excluded from conditions of symmetry...” (Emphasis added.) Indeed, the limitations

excluded from conditions of symmetry apply to the features forming the outer contour of the capsule. As such, Applicant submits that the location of the structures is, therefore, clear and that the features being excluded from the conditions of symmetry are part of the capsule being used in amended independent claim 16. As such, Applicant submits that amended claim 16 is definite.

The Examiner rejected claim 17 for failing to provide antecedent basis for several limitations. The Examiner also alleged that “[a] capsule for holding a pharmaceutical composition” in line 1 and “produced by the sealing of the seams” in line 7 are confusing as claiming the method of making a capsule structure in an apparatus claim. Applicant has amended claim 17 to provide antecedent basis as suggested by the Examiner. However, Applicant submits that the recitation of “angles of taper up to 5” degrees has sufficient antecedent basis. Applicant amended independent claim 17 to recite “[a] capsule for holding a pharmaceutical composition, the capsule which, in a closed state”. As such, “which” is clearly referring to the capsule. Applicant amended claim 17 to recite “any seams comprising sealed seams...” Applicant submits that “[a] capsule for holding a pharmaceutical composition” is clear and submits that amended claim 17 does not claim the method of making a capsule structure. Further, Applicant amended claim 17 to recite only one “and/or” for grammatical correctness.

Further pertaining to independent claim 17, Applicant submits that the meaning of the words and/or phrases “fine structures...”, “elements...”, and “angles...” are clear because the “fine structures...”, “elements...”, and “angles...” are features that *form the outer contour of the capsule*. Amended independent claim 17 recites “the following features forming the outer contour of the capsule being excluded from conditions of symmetry...” (Emphasis added.) Indeed, the limitations excluded from conditions of symmetry apply to the features forming the outer contour of the capsule. As such, Applicant submits that the location of the structures is, therefore, clear and that the features being excluded from the conditions of symmetry are part of the capsule being used in amended independent claim 17. As such, Applicant submits that amended claim 17 is definite.

In view of the above, Applicant submits that claims 1 and 4-21 clearly point out and distinctly claim the subject matter which Applicant regards as the invention. Accordingly, Applicant respectfully requests that the Examiner’s §112, second paragraph, rejection be withdrawn.

Claim Rejections under 35 U.S.C. §102(b):

At page 5 of the Office Action, the Examiner rejected claims 1, 4-9, and 17-18 under 35 U.S.C. §102(b) as being anticipated by Hochrainer et al. (U.S. Pat. Pub. 2001/0008637) (hereinafter referred to as the “‘637 reference”). Applicant respectfully traverses the rejection.

Applicant amended independent claims 1 and 17 to include the subject matter of claim 2 regarding a Bernoulli inhaler. As such, amended independent claims 1 and 17 recite a capsule containing a “composition in a Bernoulli inhaler.” Applicant respectfully acknowledges and agrees with the Examiner (page 7 of the Office Action) that the ‘637 reference lacks a Bernoulli inhaler. As such, Applicant submits that the ‘637 reference does not disclose or suggest each and every element of independent claims 1 and 17 as claimed and that amended independent claims 1 and 17 are patentable.

As claims 4-9 and 18 depend from independent claims 1 and 17, respectively, and recite additional patentable features, the subject claims are, therefore, likewise patentable. Accordingly, Applicant respectfully requests that the Examiner’s §102(b) rejection be withdrawn.

Claim Rejections under 35 U.S.C. §103(a):

At page 7 of the Office Action, the Examiner rejected claims 2, 3, 10, 19, and 20 under 35 U.S.C. §103(a) as being obvious over the ‘637 reference. Applicant respectfully traverses the rejection.

As independent claims 1 and 17 now contain the features of claim 2, Applicant will address the rejection of that claim despite cancellation thereof. The Examiner concedes that the ‘637 reference does not disclose or suggest that the inhaler is a Bernoulli inhaler. The Examiner refers to page 3, lines 26-28 of the instant application, for the motivation to use a Bernoulli inhaler – where the disclosure states that “it is an aim of the present invention to provide disposable capsules as an active substance reservoir for powder inhalers, particularly powder inhalers operating by the Bernoulli effect, which behave identically irrespective of their positioning.” (Emphasis added.) The Examiner further alleges that because the ‘637 reference teaches in paragraph [0002], line 4 that capsules can be used in a powder inhaler, the powder inhaler of the ‘637 reference is a Bernoulli inhaler. Applicant respectfully disagrees with the Examiner.

Applicant submits that the ‘637 reference does not disclose or suggest a Bernoulli inhaler and that the Examiner improperly relies on the specification of the instant application to support a

rejection through impermissible hindsight. Under MPEP § 2142, “[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.” Additionally under MPEP §2142, “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” (Emphasis added.) The Examiner does not present evidence supporting the subject allegation that the ‘637 reference discloses or suggests a Bernoulli inhaler. Thus, the Examiner fails to present a *prima facie* case of obviousness. When reviewing prior art, the Examiner must take “into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure.” *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971) (Emphasis added.). However, as aforementioned, the Examiner is in fact looking to the disclosure of the present invention for facts rather than to the prior art because the prior art does not contain evidence to support the Examiner’s allegation. Indeed, the Examiner conceded that the ‘637 reference lacks a disclosure of a Bernoulli inhaler, and the Examiner cites to the specification of the instant application for the motivation to use a Bernoulli inhaler in combination with a symmetrical capsule, not to the prior art as required under MPEP §2142. As such, Applicant submits that the Examiner is employing impermissible hindsight. *See W.L. Gore and Assoc. v. Garlock Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983). As such, Applicant submits that the ‘637 reference does not disclose or suggest each and every element of amended independent claims 1 and 17, which include the subject matter of cancelled claim 2, as claimed and that independent claims 1 and 17 are patentable. In view of the above, Applicant submits that claims 10, 19, and 20, which depend upon amended independent claims 1 and 17, respectively, are, therefore, likewise patentable.

At page 8 of the Office Action, the Examiner rejected claims 11-15 under 35 U.S.C. §103(a) as being obvious over the ‘637 reference in view of Hochrainer et al. (U.S. Pat. No. 5,947,118) (hereinafter referred to as the “‘118 patent”). Applicant respectfully traverses the rejection. The patentability of amended independent claim 1 was discussed above. The ‘118 patent does not cure the aforementioned deficiencies of the ‘637 reference. As such, Applicant submits that the teachings of the ‘637 reference and the ‘118 patent, alone or in combination, do not suggest the present invention, and that claims 11-15, which depend upon amended independent claim 1, are, therefore, likewise patentable.

At page 10 of the Office Action, the Examiner rejected claim 16 under 35 U.S.C. §103(a) as being obvious over the '118 patent in view of the '637 reference. Applicant respectfully traverses the rejection. Amended independent claim 16 recites "[a] Bernoulli inhaler for administering a composition..." As the '637 references does not disclose or suggest a Bernoulli inhaler and as the '118 patent does not cure the deficiency of the '637 reference, the teachings of the '637 reference and the '118 patent, alone or in combination, do not suggest the present invention. As such, Applicant submits that amended independent claim 16 is, therefore, patentable.

Accordingly, in view of the above, Applicant respectfully requests that the Examiner's §103(a) rejections be withdrawn.

New Claim 21:

Applicant added new independent claim 21, which includes the subject matter of claims 2 and 3 and recites a "Bernoulli inhaler". As such, Applicant submits that independent claim 21 is, therefore, likewise patentable over the cited art.

Conclusion:

In view of the foregoing, Applicant submits that the instant claims are in condition for allowance. Early and favorable action is earnestly solicited. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

Dated: April 21, 2008

Respectfully submitted,

By: s/Matthew B. Dernier/
Matthew B. Dernier
Registration No.: 40,989
KAPLAN GILMAN GIBSON & DERNIER LLP
900 Route 9 North, Suite 104
Woodbridge, New Jersey 07095
(732) 634-7634
Attorneys for Applicant